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Facsimile # (only if sent via facsimile)
Daniel B. Schein
Daniel B. Schein, Ph.D., Esq., Reg. No. 33,551
8 April 2004
Date of Signature

Our Case No.: 11190-10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ricardo de Carvalho, M.D.

Serial No.: 10/801,508

Filing Date: March 15, 2004

For: AN IMPLANTABLE AND
SEALABLE MEDICAL DEVICE
FOR UNIDIRECTIONAL
DELIVERY OF THERAPEUTIC
AGENTS TO TISSUES

Examiner: To be assigned

Group Art Unit No.: To be assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the document(s) listed on the attached Form PTO-1449 be considered by the Examiner and made of

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record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. § 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This Information Disclosure Statement is being filed prior to the receipt of the first Official Action reflecting an examination on the merits and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). Therefore, no fees are believed to be due in connection with filing of this Information Disclosure Statement.

Applicant(s) respectfully request that the listed document(s) be made of record in the present case.

Respectfully submitted,

8 April 2004
Date

Daniel B. Schein
Daniel B. Schein, Ph.D., Esq.
Registration No. 33,551
Attorney for Applicant

Daniel B. Schein
P.O. Box 28403
San Jose, CA 95159

Telephone: (408) 294-6750
Facsimile: (408) 294-6752



FORM PTO-14	SERIAL NO. 10/801,508	CASE NO. 11190-10
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE March 15, 2004	GROUP ART UNIT
(use several sheets if necessary)		APPLICANT(S): Carvalho et al.

REFERENCE DESIGNATION			U.S. PATENT DOCUMENTS			
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	1	4,309,776	January 12, 1982	Berguer		
	2	4,378,016	March 29, 1983	Loeb		
	3	4,479,796	October 30, 1984	Kallok		
	4	5,182,111	January 26, 1993	Aebischer et al.		
	5	5,411,550	May 2, 1995	Herweck et al.		
	5	5,725,493	March 10, 1998	Avery et al.		
	6	5,830,173	November 3, 1998	Avery et al.		
	7	5,836,935	November 17, 1998	Ashton et al.		
	8	5,902,598	May 11, 1999	Chen et al.		
	9	6,001,386	December 14, 1999	Ashton et al.		
	10	6,217,895	April 17, 2001	Guo et al.		
	11	6,251,090	June 26, 2001	Avery et al.		
	12	6,413,540	July 2, 2002	Yaacobi		
	13	6,416,777	July 9, 2002	Yaacobi		

PUBLISHED U.S. PATENT APPLICATIONS					
EXAMINER INITIAL		DOCUMENT NUMBER	PUB. DATE	NAME	FILING DATE
	14	20030069560 A1	April 10, 2003	Adamis, et al.	MAY 2, 2002
	15	20030064088 A1	April 3, 2003	Carvalho et al.	August 28, 2002

U.S. PROVISIONAL PATENT APPLICATIONS					
		SERIAL #	FILING DATE	NAME	
	15	60/334,177	11/29/2001	Borenstein et al.	
	16	60/332,200	11/21/2001	Borenstein et al.	
	17	60/332,199	11/21/2001	Borenstein et al.	
	18	60/291,445	05/16/2001	Borenstein et al.	
	19	60/291,340	05/16/2001	Borenstein et al.	
	20	60/288,373	05/03/2001	Borenstein et al.	

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES NO

EXAMINER INITIAL	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)	
	21	Torres-Lugo, Madeline., et al., "Transmucosal delivery systems for calcitonin: a review", <i>Biomaterials</i> , Vol. 21, pages 1191-1196 (2000) —
	22	Benes, L., et al., "Transmucosal, Oral Controlled-Release, and Transdermal Drug Administration in Human Subjects: A Crossover Study with Melatonin", <i>Journal of Pharmaceutical Sciences</i> , Vol. 86, No. 10, pages 1115-1119 (1997) —
	23	Gebhardt, Bryan M., et al., "Collagen as a Delivery System for Hydrophobic Drugs: Studies with Cyclosporine", <i>Journal of Ocular Pharmacology and Therapeutics</i> , Vol. 11, No. 3, Pages 319-327 (1995) —
	24	Kanpolat, Ayfer., et al., "Penetration of Cyclosporin A into the Rabbit Cornea and Aqueous Humor after Topical Drop and Collagen Shield Administration", <i>The CLAO Journal</i> , Vol. 20, No. 2, pages 119-122 (1994) —
	25	Lehr, C-M., "From sticky stuff to sweet receptors – Achievements, limits and novel approaches to bioadhesion", <i>European Journal of Drug Metabolism and Pharmacokinetics</i> , Vol. 21, No. 2, Pages 139-148 (1996) —
	26	Rudnick, David E., et al., "The effect of Intraocular Pressure on Human and Rabbit Scleral Permeability", <i>IOVS</i> , Vol. 40, NO. 12, pages 3054-3058 (1999) —
	27	Olsen, Timothy W., et al., "Human Sclera: Thickness and Surface Area", <i>American Journal of Ophthalmology</i> , Vol. 125, No. 2, Pages 237-241 (1998) —
	28	Olsen, Timothy W., et al., "Human Scleral Permeability", <i>Investigative Ophthalmology & Visual Science</i> , Vol. 36, No. 9, pages 1893-1903 (1995) —
	29	Brem, Henry., et al., "Placebo-controlled trial of safety and efficacy of intraoperative controlled delivery by biodegradable polymers of chemotherapy for recurrent gliomas", <i>The Lancet</i> , Vol. 345, pages 1008-1012 (1995) —
	30	Valtonen, Simo., et al., "Interstitial Chemotherapy with Carmustine-loaded Polymers for High-grade Gliomas: A Randomized Double-blind Study Clinical Study", <i>Neurosurgery</i> , Vol. 41, No. 1, pages 44-49 (1997) —
	31	Subach, Brian R., et al., "Morbidity and Survival after 1,3-bis(-chloroethyl)-1- Nitrosourea Wafer Implantation for Recurrent Glioblastoma: A Retrospective Case-matched cohort series", <i>Neurosurgery</i> , Vol. 45, No. 1, pages 17-23 (1999) —
	32	Moriya, T., et al., "Controlling Malignant Pericardial Effusion by Intrapericardial carboplatin Administration in Patients with Primary Non-Small-Cell Lung Cancer", <i>British Journal of Cancer</i> , Vol. 83, No. 7, pages 858-862 (2000) —
	33	Lerner-Tung, Mary B., et al., "Pharmacokinetics of intrapericardial administration of 5-fluorouracil", <i>Cancer Chemother Pharmacol</i> , Vol. 40, pages 318-320 (1997) —
	34	Darsinos, J. TH., et al., "Distribution of lidocaine and digoxin in heart tissues and aorta following intrapericardial administration", <i>International Journal of Clinical Pharmacology, Therapy and Toxicology</i> , Vol. 31, No. 12, pages 611-615 (1993) —

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EXAMINER INITIAL	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)	
	35	Darsinos, J. T., et al., "Distribution of amiodarone in heart tissues following intrapericardial administration", <i>International Journal of Clinical Pharmacology and Therapeutics</i> , Vol. 37, No. 6, pages 301-306 (1999) -
	36	Uchida, Y., et al., "Angiogenic therapy of acute myocardial infarction by intrapericardial injection of basic fibroblast growth factor and heparin sulfate: An experimental study", <i>American Heart Journal</i> , Volume 36, No. 6, pages 1182-1188 (1995) -
	37	Laham, Roger J., "Intrapericardial Administration of Basic Fibroblast Growth Factor: Myocardial and Tissue Distribution and Comparison With Intracoronary and Intravenous Administration", <i>Catheterization and Cardiovascular Interventions</i> , Vol. 58, pages 375-381 (2003) -
	38	D'Hermies, Francois., et al., "Scleral and episcleral histological changes related to encircling explants in 20 eyes", <i>ACTA Ophthalmologica Scandinavica</i> , Vol. 77, pages 279-285 (1999) -
	39	D'Hermies, Francois., et al., "Encapsulation of Scleral Buckling Materials", <i>Ophthalmology</i> , Vol. 105, No. 6. (1998) -
	40	Ricci, Benedetto., et al., "Octyl 2-cyanoacrylate tissue adhesive in experimental scleral buckling", <i>Acta Ophthalmol. Scand.</i> , Vol. 78, pages 506-508 (2001) -
	41	Korobelnik, J. F., "Expanded Polytetrafluoroethylene Episcleral Implants Used as Encircling Scleral Buckling", <i>Ophthalmic Res</i> , Vol. 32, pages 110-117 (2000) -
	42	Mulvihill, Alan., et al. "Ocular Motility Changes After Subtenon Carboplatin Chemotherapy for Retinoblastoma", <i>Arch Ophthalmol.</i> Vol. 121, pages 1120-1124 (2003) -
	43	D'Hermies, F., "Alterations Anatomopathologiques Liees Au Traitement Par Cerclage Des Golbes Oculaires Atteints De Decollement De Retine", <i>Societe D'edition de l'Association de l'Enseignement Medical des Hopitaux de Paris</i> . Pages 215-222 (1999) -
	44	Korobelnik, J. F. et al., "e-PTFE as Scleral Buckling Episcleral Implants: An Experimental and Histopathologic Study", <i>John Wiley & Sons, Inc. J Biomed Mater Res</i> Vol. 48, pages 807-813 (1999) -
	45	D'Hermies, F. et al., "Experimental Encircling Scleral Buckle With Silicone and Hydrogel", <i>The Journal of Retinal and Vitreous Diseases</i> . Vol. 19 No. 2, pages 148-157 1999 /S.A./
	46	D'Hermies, F. et al., "Miragel Versus Silastic Used As Episcleral Implants in Rabbits", <i>Retina</i> Vol. 15 No. 1 Pages 62-67 (1995) -
	47	Spitznas, M. et al., "Retinal Surgery Using Cyanoacrylate as a Routine Procedure", <i>Arch. Klin. exp. Ophtal.</i> Vol. 187, pages 89-101 (1973) ✓
	48	Calabria, G. et al., "Sutureless Scleral Buckling", <i>Arch Ophthalmol.</i> Vol. 83, pages 613-618 (1970) ✓
	49	Calabria, G. et al., "Further Experience With Sutureless Scleral Buckling Materials", <i>Arch Ophthalmol.</i> Vol. 86, pages 82-87 (1971) -
	50	Olsen, T.W. et al., "An Evaluation of an Episcleral Anecortave Acetate Transscleral Drug Delivery System in Rhesus Monkey", <i>Invest Ophthalmol Vis Sci</i> . Vol. 44, page 4213 (2003) -
	51	Yaacobi, Y. et al., "In-Vivo Studies with Trans-Scleral Anecortave Acetate Delivery Device Designed to Treat Choroidal Neovascularization in AMD", <i>Invest Ophthalmol Vis Sci</i> . Vol. 44, page 4210 (2003) -
	52	Olsen, T. et al., "Human Sclera: Thickness and Surface Area", <i>American Journal of Ophthalmology</i> . Vol. 125. No. 2, pages 237-241 (1998) -
	53	Harbour, J. et al., "Transducible Peptide Therapy for Uveal Melanoma and Retinoblastoma", <i>Arch Ophthalmol.</i> Vol. 120, pages 1341-1346 (2002) -

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	54	Sayani, A. et al., "Systemic Delivery of Peptides and Proteins Across Absorptive Mucosae", <i>Therapeutic Reviews™ in Therapeutic Drug Carrier Systems</i> . 13(1&2): 84-185 (1996) —

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